

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

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	:	Honorable Brian R. Martinotti, U.S.D.J.
IN RE SELENIOUS ACID LITIGATION	:	
	:	Civil Action No. 24 CV 7791 (BRM) (CLW)
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CONFIDENTIALITY ORDER

WHEREAS, Plaintiff American Regent, Inc. (“ARI”) and Defendant Accord Healthcare, Inc. (“Accord”), Defendant Aspiro Pharma Ltd. (“Aspiro”), Defendants Cipla USA, Inc. and Cipla Limited (collectively, “Cipla”), Defendants Dr. Reddy’s Laboratories, Inc. and Dr. Reddy’s Laboratories, Ltd. (collectively, “DRL”), Defendant Gland Pharma Ltd. (“Gland”), Defendant Hikma Pharmaceuticals USA Inc. (“Hikma”), Defendant RK Pharma, Inc. (“RK Pharma”), Defendants Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC (collectively, “Somerset”), Defendants Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc. (collectively, “Sun”), Defendants Xiromed, LLC and Xiromed Pharma España, S.L. (collectively, “Xiromed”), and Defendant Zydus Pharmaceuticals (USA) Inc. (“Zydus”) (together, “Defendants”) are parties (ARI and Defendants collectively, the “Parties”) to the above-referenced patent infringement case (the “Litigation”);

WHEREAS, the Parties believe that one or more of them will or may be required to disclose to another Party certain documents, things, and information that constitute or contain trade secrets, technical know-how, or other confidential or proprietary research, development, business, commercial, or financial information relating to the subject matter of the Litigation;

WHEREAS, the Parties consider such information to be confidential and proprietary within the meaning of Fed. R. Civ. P. 26(c)(1)(G) and, therefore, desire that a Confidentiality Order limiting use, access to, and disclosure of such information be entered;

WHEREAS, the Parties have exchanged and/or expect to exchange discovery in connection with this case and recognize that confidential information may be disclosed in the course of discovery;

WHEREAS, the Parties desire to limit the extent of disclosure and use of such confidential information, and to protect such confidential information from unauthorized use and/or further disclosure, and wish to ensure that no advantage is gained by any of the Parties by the use of such confidential information which could not have been gained had discovery in this case not occurred;

WHEREAS, this case involves highly technical subject matter potentially involving discovery of trade secrets and proprietary information pertaining to, among other things, drug formulations, manufacturing processes and techniques, scientific research and development, financial records, and other sensitive competitive information; and

WHEREAS, each of the Parties has consented to the entry of this Confidentiality Order pursuant to Fed. R. Civ. P. 26(c)(1)(G), Local Patent Rule 2.2, and Local Civil Rule 5.3 and the Court having considered the foregoing and for good cause shown,

IT IS on this 30th day of January, 2025,

ORDERED, that the following provisions shall govern the conduct of further proceedings in the Litigation:

A. DEFINITIONS

1. (a) The term “Confidential Information” shall mean any form of trade secret or other confidential research, development, or commercial information within the meaning of Fed. R. Civ. P. 26(c)(1)(G). The designation of Confidential Information by a Producing Party (as defined below) constitutes its representation that it reasonably and in good faith believes that the designated material constitutes or contains information in one or more of the foregoing categories within the meaning of Fed. R. Civ. P. 26(c)(1)(G). Further, Confidential Information includes: (a) all copies, extracts, and complete or partial summaries prepared from Confidential Information, and (b) portions of briefs, memoranda, or any other writings filed/submitted with the Court and exhibits thereto that contain, summarize, or reflect the content of any such Confidential Information. Confidential Information includes information that is of such a sensitive nature that it supports a reasonable and good faith belief that granting access to such information to an employee or officer of a competitor will place the Producing Party at a competitive disadvantage.

(b) The term “Defendant Group” shall mean one of the groups of Defendants as listed below (and, collectively, referred to as “Defendant Groups”):

1. “Accord Defendant Group” shall mean Accord Healthcare, Inc.
2. “Aspiro Defendant Group” shall mean Aspiro Pharma Ltd.
3. “Cipla Defendant Group” shall mean Cipla USA, Inc. and Cipla Limited.
4. “DRL Group” shall mean Dr. Reddy’s Laboratories, Inc. and Dr. Reddy’s Laboratories, Ltd.
5. “Gland Defendant Group” shall mean Gland Pharma Ltd.
6. “Hikma Defendant Group” shall mean Hikma Pharmaceuticals USA Inc.
7. “RK Pharma Defendant Group” shall mean RK Pharma, Inc.

8. “Somerset Defendant Group” shall mean Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC.

9. “Sun Defendant Group” shall mean Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc.

10. “Xiromed Defendant Group” shall mean Xiromed, LLC and Xiromed Pharma España, S.L.

11. “Zydus Defendant Group” shall mean Zydus Pharmaceuticals (USA) Inc.

Each Defendant Group shall be considered as a single “Party” for purposes of marking CONFIDENTIAL INFORMATION as a “Producing Party,” receiving CONFIDENTIAL INFORMATION as a “Receiving Party,” and, to the extent permitted in this Confidentiality Order, to object on behalf of a Party. If additional defendants are added to this action, they shall be included in the appropriate existing Defendant Group, or to the extent newly added defendants are not related, either directly or indirectly, to an existing Defendant Group, one or more new Defendant Groups shall be created without the need for formal modification of this Confidentiality Order.

(c) The term “Party” means any one of ARI, Accord, Aspiro, Cipla, DRL, Gland, Hikma, RK Pharma, Somerset, Sun, Xiromed, and/or Zydus.

(d) The term “Producing Party” means a Party or nonparty producing and designating information, documents, or things as Confidential Information under this Confidentiality Order.

(e) The term “Designating Party” means a Party or nonparty designating information, documents, or things as Confidential Information under this Confidentiality Order. The terms “Producing Party” and “Designating Party” shall not be deemed to be mutually exclusive.

(f) The term “Non-Designating Party” means, with respect to information, documents, or things designated as Confidential Information under this Confidentiality Order, a Party or nonparty that did not designate that document or information as Confidential Information under this Confidentiality Order.

(g) The term “Receiving Party” means the Party receiving any information, document, or thing designated as Confidential Information under this Confidentiality Order.

B. DESIGNATION OF CONFIDENTIAL INFORMATION

2. Each Producing Party who produces or discloses any material that it believes comprises Confidential Information may so designate it by marking the document, information, thing, or portion thereof containing the information “CONFIDENTIAL.” For non-written material, such as recordings, magnetic media, photographs, and things, a legend substantially in the above form referenced in this Paragraph shall be affixed to the material, or a container for it, in any suitable manner. A Designating Party may also designate material as “CONFIDENTIAL” in accordance with this Paragraph.

3. When documents are produced for inspection, the documents shall be treated by the Receiving Party as Confidential Information unless or until copies of the documents are provided. Deposition testimony will be treated as Confidential Information unless otherwise designated, confidentiality is waived or reduced either on the record during the deposition or within thirty (30) calendar days after receipt of the final transcript, or the Court orders that such testimony is not Confidential Information. For the avoidance of doubt, if no designation is made on the record during the deposition or by the expiration of the thirty (30) calendar days after receipt of the final transcript, the Receiving Party need not treat the deposition testimony as Confidential Information. Each transcript containing Confidential Information shall be prominently marked on the front page with a state that provides “THIS DEPOSITION

TRANSCRIPT CONTAINS CONFIDENTIAL INFORMATION SUBJECT TO CONFIDENTIALITY ORDER.” For non-written material, such as recordings, magnetic media, photographs, and things, a legend substantially in the above form shall be affixed to the material, or a container for it, in any suitable manner.

4. If any Confidential Information is produced by a nonparty in this case, such nonparty shall be considered a Producing Party within the meaning of that term as it is used in the context of this Order, and each of the Parties shall be treated as a Receiving Party. Confidential Information that originated with a nonparty may be designated as such and shall be subject to the restrictions on disclosure specified herein.

5. In the event any Producing Party produces Confidential Information that has not been designated as such or not been correctly designated, the Producing Party may designate or re-designate the information to the same extent as it may have designated the information before production, by a subsequent notice in writing specifically identifying the re-designated information, in which event the Parties shall henceforth treat such information in accord with this Order, and shall undertake their best efforts to correct any disclosure of such information contrary to the re-designation, including retrieving any documents from persons not qualified to receive them under the re-designation and informing such persons that they should not further use or disseminate the information therein. No demonstration or proof of error, inadvertence, or excusable neglect by the Producing Party shall be required for such re-designation, with the following exception: corrections to the designation of documents or information used in hearings or trial must be made contemporaneously or else are waived, but only in situations where the nature of the hearing or trial would otherwise be inconsistent with the designation sought (by way of non-limiting example, re-designation must be contemporaneous in a public hearing where

a Party seeks to designate a document as “CONFIDENTIAL,” but re-designation need not be contemporaneous in a sealed hearing where a Party seeks to designate a document as “CONFIDENTIAL”). If any document or information is: used during a deposition; used as an exhibit to a filing with the Court; or identified for potential use at trial, including in expert reports or discovery responses, then the Producing Party will be entitled to relief under Paragraph 5 only if the Producing Party makes a claim of inadvertent production within thirty (30) calendar days after such use or identification of the document or information.

6. A Party shall not be obligated to challenge the propriety of any designation of Confidential Information at the time the designation is made, and failure to do so shall not preclude a subsequent challenge to the designation. In the event that any Party disagrees at any stage of the Litigation with any designation, that Party shall provide written notice of its disagreement with the designation to the Producing Party or Designating Party, as appropriate. The Parties, and nonparty as applicable, shall first try to dispose of such dispute in good faith on an informal basis without judicial involvement. If the dispute cannot be resolved, the Party challenging the designation may request appropriate relief from the Court within ten (10) business days after written notice is provided, provided such request is in accordance with Local Civil Rule 37.1. The burden of proving that information has been properly designated is on the Producing Party or Designating Party, as appropriate. However, the Parties agree that designating information as Confidential Information is improper if such information (i) can be shown to be generally available to the public at the time of such designation; (ii) becomes part of the public domain or publicly known or available by publication or otherwise not as the result of any unauthorized act or omission on the part of the Non-Designating Party or Receiving Party; or

(iii) is thereafter disclosed to the Non-Designating Party or Receiving Party by a third party as a matter of right.

C. DISCLOSURE AND USE OF CONFIDENTIAL INFORMATION

7. Subject to Paragraphs 13-18, Confidential Information of the Producing Party or Designating Party may be disclosed, summarized, described, revealed, or otherwise made available in whole or in part only in accordance with the terms of this Confidentiality Order, and only to the following persons:

a) Outside counsel for any of the Parties, and employees of such counsel, who, after receipt of any material that has been designated as Confidential Information, and in addition to the other terms of this Confidentiality Order, shall not use any other Party's or any nonparty's Confidential Information for any purpose other than in connection with the Litigation;

b) Up to three (3) designated in-house legal representatives employed by each Party, as well as their support staff, subject to paragraph 8, who have a need to know Confidential Information to fulfill their duties and responsibilities in connection with this case, provided such employees have complied with Paragraph 16 hereof, the designated in-house legal representatives for the Parties being as follows or as otherwise identified during the course of this case:

For ARI:

For Accord:

For Aspiro:

For Cipla:

For DRL:

For Gland:

For Hikma:

For RK Pharma:

For Somerset:

For Sun:

For Xiromed:

For Zydus:

who, after receipt of Confidential Information, and in addition to the other terms of this Confidentiality Order, shall not use any other Party's or any nonparty's Confidential Information for any purpose other than in connection with the Litigation, and shall not disclose any other Party's or any nonparty's Confidential Information to any third party, including, but not limited to, the United States Food & Drug Administration and the United States Patent and Trademark Office;

c) independent experts and consultants retained to assist outside counsel for the Parties in the conduct of this case, provided such persons have complied with Paragraph 16 hereof, as well as the staff of any such independent experts and consultants;

d) corporate designees under Fed. R. Civ. P. 30(b)(6) of the Producing Party or Designating Party, but only at deposition or trial, and only with respect to the information of that Producing Party or Designating Party;

e) authors or drafters; addressees; anyone who received the specific Confidential Information prior to the commencement of this action; anyone who received the specific Confidential Information during this action but only if they obtained the Confidential Information independently and outside of this action and not in violation of this Confidentiality Order; and current or former directors, officers, employees, or

corporate designees of the Producing Party (or Designating Party, as applicable), but only if the Confidential Information was in existence during the period of his or her service or employment and foundation is established that he or she was involved in the project to which the Confidential Information relates, and that he or she had access to the Confidential Information during the course of his or her service or employment) and their counsel, provided that the information was authored by, created by, addressed to, received by, signed by, or is otherwise established to have been known to the current or former director, officer, employee, or corporate designee of the Producing Party (or Designating Party, as applicable); but only at deposition, trial, or court hearing, and for the good faith preparation therefor;

- f) the Court and court personnel;
- g) court reporters and videographers and their staff;
- h) vendors and photocopy services retained by or for any of the Parties to assist in preparing for discovery, trial, and/or hearings in this case;
- i) professional translators who are retained by outside counsel for the Parties for the purposes of this case;
- j) graphics or design consultants retained to prepare demonstratives or other exhibits for use in this case;
- k) professional jury or trial consultants and persons employed or retained by them solely in providing litigation support services to outside counsel for the Parties for the purposes of this case;
- l) document imaging and database services and consultants retained to set up, maintain, and/or operate litigation databases for this case; and

m) any other persons as ordered by the Court or to whom the Producing Party or Designating Party, as applicable, has given written consent.

8. Other than as set forth in this Paragraph 8, any person permitted access to Confidential Information of a Defendant Group shall not produce or otherwise disclose such Confidential Information to any other Defendant Group without first obtaining (1) consent from the producing Defendant Group, or (2) an order from the Court. For clarity, in-house employees of a Defendant Group under Paragraph 7(b) shall not receive Confidential Information of any other Defendant Group without first obtaining (1) consent from the producing Defendant Group, or (2) an order from the Court.

ARI is permitted to include Confidential Information of one or more Defendant Group in any court pleadings, filings, briefs, letters, expert reports, discovery requests and responses, and contentions provided that ARI serves on all Defendant Groups (1) a clean copy marked on the front page as **“For Defendants¹, Outside Counsel Only. Contains Confidential Information of”** followed by a list of the Defendant Group(s) whose Confidential Information is included in the document, and (2) a copy that highlights in yellow all of Defendants’ Confidential Information and is marked on the front page as **“For Defendants, Outside Counsel Only. Contains Confidential Information of”** followed by a list of the Defendant Group(s). Both copies shall be served only on persons designated to receive Confidential Information under Paragraph 7(a) (*i.e.*, outside counsel). Representatives of each Defendant Group whose Confidential Information has been highlighted will identify to ARI what highlighted material should be redacted. After ARI receives confirmation from each Defendant Group for which ARI

¹ For the avoidance of doubt, documents and things marked under this designation may be disclosed to ARI’s in-house counsel identified in Section C.7(b), *supra*.

identified Confidential Information about the extent of redaction necessary, ARI shall provide a redacted copy that may be provided to authorized recipients of Confidential Information.

A Party may use the Confidential Information of any Defendant Group at a court hearing, deposition, or at trial attended by persons permitted access under Paragraph 7(a) or independent experts permitted access under Paragraph 7(c), on a strictly Outside Counsel's Eyes Only basis with respect to Defendants, to the extent otherwise permitted under this Confidentiality Order, whether or not that counsel or independent expert was retained by that Defendant Group. For the avoidance of any doubt, nothing in this clause prohibits individuals designated under Paragraph 7(b) for ARI from attending a court hearing, deposition, or trial in which the Confidential Information from any Defendant Group is used.

9. Subject to Paragraphs 13-18, any person associated with ARI or Defendants permitted to receive Confidential Information pursuant to Paragraph 7 herein, who obtains, receives, has access to, or otherwise learns, in whole or in part, Confidential Information under this Order:

a) shall not prepare, prosecute, or assist in the drafting or amending of patent claims in any domestic or foreign patent application or any post-grant proceeding pertaining to products containing selenious acid or methods of use thereof during the pendency of this case and for one year after the conclusion of this case, including any appeals (for the avoidance of any doubt, a person receiving Confidential Information can represent a party and otherwise participate in a post-grant proceeding before the United States Patent and Trademark Office, but cannot participate in the amendment of any claims); and

b) shall not prepare or assist in the drafting of any correspondence or communications with U.S. Food & Drug Administration (“FDA”) concerning any Citizen’s Petitions with respect to New Drug Application (“NDA”) No. 209379 or any Abbreviated New Drug Applications (“ANDA”) that does or may reference NDA No. 209379 or rely upon data from NDA No. 209379 during the pendency of this case and for one year after the conclusion of this case, including any appeals. Nothing in this paragraph shall be construed to prohibit an individual from communicating with or providing submissions to the FDA on behalf of a Party relating to that Party’s own ANDA or NDA, including responding to any Citizen Petition relating to that Party’s own ANDA or NDA, so long as such individual does not use Confidential Information received from any other Party in this action in connection with such submission; and

c) shall not have competitive decision-making authority relating to the research, development, manufacturing, or sales and marketing of selenious acid. Nothing in this paragraph shall be construed to prohibit legal representatives from providing advice related to that Party’s own ANDA or NDA (or ANDA or NDA product), so long as such legal representatives otherwise comply with the provisions of this Confidentiality Order.

10. Nothing in this Confidentiality Order shall prevent disclosure of Confidential Information if the Producing Party or Designating Party, as applicable, consents to such disclosure or if the Court, after notice to all Parties (and if applicable, nonparty), orders such disclosure.

11. All Confidential Information disclosed pursuant to this Order shall be used by a Receiving Party solely for the purposes of the Litigation and not for any business, regulatory,

commercial, or competitive purposes, including, but not limited to, filing or prosecuting patent applications or any communicating or petitioning activity with FDA or another regulatory agency.

12. It shall be the duty of each Party and each individual having notice of this Confidentiality Order to comply with this Confidentiality Order from the time of such notice.

13. By written agreement of the Parties, or upon motion and order of the Court, the list of individuals designated under this Confidentiality Order to whom Confidential Information may be disclosed may be modified or expanded. Parties can replace any in-house designee listed in Paragraph 7(b) at any time during this Litigation without the written agreement of the Parties or motion and order of the Court, so long as all Parties to the Litigation are notified and the replaced in-house designee has complied with Paragraphs 16 and 17 hereof, and the Parties have complied with Paragraph 18 hereof.

14. If a Producing Party or Designating Party seeks to protect Confidential Information from public disclosure or use during a trial, court appearance, or hearing which is open to the public (a “Court Disclosure”), the Producing Party or Designating Party shall make an application to the Court to restrict such disclosure or use, unless consent from the Receiving Party is previously obtained. Such application may be made at any time before the Court Disclosure, within ten (10) business days after the Court Disclosure, or as otherwise permitted by the Court.

15. Any Party filing any document, material, or information designated by another party as “CONFIDENTIAL” shall comply with Local Civil Rule 5.3(c) to seal such document, material, or information to prevent public disclosure. Before filing any redacted public copy, a “proposed redacted copy” shall be provided to the Producing Party(ies), reasonably in advance of

the filing deadline, to allow additional redactions to be designated and/or unnecessary redactions to be removed. The Parties will work together in good faith to jointly prepare the motion and supporting documents required by Local Civil Rule 5.3(c)(3) and, should the need arise, will seek additional time to file the motion and/or any redacted public copy.

16. No person identified in Paragraph 7(b) shall be given access to Confidential Information unless such person shall first have signed a Declaration of Compliance with this Order in the form attached as **Exhibit A** hereto. No person identified in Paragraph 7(c) shall be given access to Confidential Information unless such person shall first have signed a Declaration of Compliance with this Order in the form attached as **Exhibit B** hereto.

17. Before any person identified in Paragraph 7(b) may be given access to Confidential Information and before any person identified in Paragraph 7(c) may be given access to Confidential Information, the Party seeking to provide such access shall deliver a copy of the Declaration referred to in Paragraph 16, fully executed by such person, and written notice (by email) to the attorneys for the Producing Party or Designating Party, as applicable, of the intention to make such disclosure. In the case of a disclosure to persons identified in Paragraph 7(b) hereof, the notice shall state the individual's name and position. In the case of a disclosure to persons identified in Paragraph 7(c) hereof, the notice shall (i) state the name and address of the person to whom disclosure is proposed, (ii) include a copy of the designated expert's resume or curriculum vitae with an identification of the person's job title and responsibilities, (iii) identify the designated expert's qualifications and a good faith listing of publications authored by the designated expert in the prior ten (10) years, and (iv) identify (by name and number of the case, and location of court) any litigation in connection with which the designated expert has offered expert testimony, including through a declaration, report, or testimony at a deposition or

trial, in the prior four (4) years. To the extent any of items (iii)–(iv) are fully disclosed in the designated expert’s resume or curriculum vitae provided under item (ii) of this Paragraph 17, such items need not also be disclosed in a separate form.

18. For proposed disclosures to persons identified in Paragraphs 7(b) and 7(c), hereof, the Producing Party or Designating Party, as applicable, within five (5) business days from receiving service of written notice provided pursuant to Paragraph 17 hereof, may object to such disclosure by delivery (by email) of a written notice of objection on the attorneys for the Party seeking to make the disclosure, stating the reasons for the objection. No disclosure of Confidential Information may occur prior to the expiration of five (5) business days from the date of service of the written notice of intent to disclose unless consent is granted earlier by the Producing Party or Designating Party, if applicable, or ordered by the Court. Consent pursuant to the provisions of this Paragraph shall not be unreasonably withheld. If the Producing Party or Designating Party objects to the disclosure and gives written notice thereof, and the Parties (and if applicable, nonparty) are unable to resolve the objection, the Party or nonparty opposing the disclosure must file a letter application to the Court pursuant to Local Civil Rule 37.1 within five (5) business days of giving the written notice of objection; otherwise, the information may be disclosed to the identified person. If such an application is made, no disclosure may be made until the objection is resolved by agreement or the Court denies the application. Failure to timely object to the disclosure based on information then disclosed in the written notice pursuant to Paragraph 17 hereof shall operate as a waiver of the objection. Waiver as to a specific disclosure shall not constitute waiver for any subsequent disclosures. In the event that an application is made, the objecting Party or nonparty shall have the burden of proving that disclosure should not occur.

19. Nothing herein shall prevent a Producing Party or Designating Party from disclosing or using its own Confidential Information in any manner that it considers appropriate. No information that is in the public domain or which is already known by the Receiving Party through proper means or which is or becomes available to a Party from a source other than the Producing Party, Designating Party, or nonparty asserting confidentiality, rightfully in possession of such information on a non-confidential basis, shall be deemed or considered to be Confidential Information material under this Confidentiality Order.

20. Nothing herein shall bar or otherwise restrict counsel from rendering advice to his or her client with respect to this case and, in the course thereof, referring to or relying upon his or her examination of Confidential Information. But in rendering such advice and in otherwise communicating with his or her client, counsel shall not (a) disclose any Confidential Information if such disclosure would be contrary to the provisions of this Confidentiality Order, or (b) disclose any summary of any Confidential Information in such detail as would violate the spirit and frustrate the purpose of this Confidentiality Order.

21. If a Receiving Party is served with a subpoena, discovery request in another action, or any other request seeking by legal process the production of information, documents, things, or other material produced to it and designated as Confidential Information in this case, such Party shall notify promptly the Producing Party and/or Designating Party so as to provide the Producing Party and/or Designating Party a reasonable opportunity to object to the production.

22. If an additional party joins or is joined in this case, the newly joined party shall not have access to Confidential Information until said party agrees to a supplemental Confidentiality Order governing the protection of Confidential Information.

23. Any nonparty from whom discovery is sought in this case may designate some or all of the information, documents, things, or other material as Confidential Information under this Confidentiality Order. If it does so, then each Party will have with respect to such Confidential Information the same obligations which that Party has with respect to Confidential Information of another Party to this case.

D. DURATION OF ORDER, OBJECTIONS, MODIFICATIONS

24. This Confidentiality Order shall remain in force and effect indefinitely until modified, superseded, or terminated by order of this Court, which may be entered pursuant to agreement of the Parties hereto. This Confidentiality Order shall continue in effect after termination of this case and continue to be binding upon all persons to whom Confidential Information is disclosed hereunder.

25. Upon final termination of this case (including all appeals) the Receiving Party shall, within sixty (60) calendar days of such termination, either return to the Producing Party or destroy all Confidential Information of any Party other than the Receiving Party in its possession, including, but not limited to, information stored in electronic form. In either event, the Receiving Party shall identify and describe the materials returned or destroyed and certify such return or destruction, with the exception that outside counsel may retain, subject to the provisions of this Confidentiality Order, all correspondence, one copy of the pleadings or other papers filed with the Court or served in the course of this case, deposition transcripts, deposition exhibits, expert reports and exhibits, hearing transcripts, any hearing or trial record (including without limitation all bench memoranda, demonstratives, and exhibits), and all documents and things containing or reflecting attorney work product and attorney-client communications. The Receiving Party is not obligated to return or destroy Confidential Information that may be

contained on electronic back-up tapes or other archival media, including email servers, which should be treated in accordance with standard retention policies, i.e., which are not retained indefinitely without being overwritten.

26. If the Receiving Party desires to disclose Confidential Information to persons not qualified to receive it under this Order or if the Receiving Party disagrees with a designation by the Producing Party or Designating Party, then the Receiving Party and the Producing Party or Designating Party shall first try to resolve such dispute. If the dispute cannot be resolved, a ruling may be sought from the Court. Pending a determination by the Court, such information shall be treated under this Order as Confidential Information as designated by the Producing Party or Designating Party.

E. NO WAIVER OF PRIVILEGES

27. If information that is otherwise properly subject to a claim of attorney-client privilege, attorney work-product immunity, joint defense privilege, common interest privilege, or any other privilege or immunity protecting it from discovery is inadvertently produced, the fact of its inadvertent production shall in no way be relied upon as a ground to support any argument that the information is no longer subject to the privilege or immunity. Nor shall such inadvertent production prejudice or otherwise constitute a waiver of, or estoppel as to, any claim of privilege, work product immunity or other ground for withholding production to which the Producing Party or other person otherwise would be entitled, either in whole or in part, in this case, or in any other proceeding. If a written claim of inadvertent production is made pursuant to this Paragraph 27, upon receipt of such written notice, the Receiving Party shall promptly destroy or return to the Producing Party (i) the inadvertently produced material, (ii) any and all copies or

reproductions thereof, and (iii) any and all copies of summaries or notes based thereon or relating thereto, of which the Receiving Party is aware.

However, if the Receiving Party wishes to challenge the claim that the information would have properly been subject to a privilege or immunity before it was inadvertently produced, it may retain one copy and must notify the Producing Party of its challenge within ten (10) business days of receiving the notice of inadvertent production, and move the Court for a ruling on the propriety of the claim of privilege or immunity within ten (10) business days of receiving the notice of inadvertent production, unless such time period is extended by mutual agreement of the Parties. During the pendency of such motion, the Receiving Party may retain the single copy but shall make no other use or disclosure of the subject material or the information contained therein. The Producing Party shall bear the burden of proving that the inadvertently produced documents or materials are privileged or immune from discovery. If the Receiving Party prevails on its challenge to the Producing Party's claim of privilege or immunity, the Producing Party shall promptly reproduce the material to the Receiving Party. If the Receiving Party does not prevail on its challenge to the Producing Party's claim of privilege or immunity, it must certify to the Producing Party within five (5) business days of the Court's decision that it has destroyed the remaining single copy.

28. If any Confidential Information is disclosed through inadvertence or otherwise by a Receiving Party to any person or party not otherwise authorized to receive such information under this Confidentiality Order, then the Receiving Party responsible for the disclosure shall (i) use its best efforts to obtain the return or destruction of such information and to bind such non-authorized person or party to the terms of this Confidentiality Order; (ii) within three (3) business days of the discovery of such disclosure, inform such person or party of all provisions

of this Confidentiality Order and request that such person or party sign the Declaration of Compliance with this Confidentiality Order in the form attached as Exhibit A or Exhibit B hereto; and (iii) within five (5) business days of the discovery of such disclosure, inform the Producing Party and/or Designating Party of all pertinent facts relevant to such disclosure, including the identity of such person, entity, or party and the information disclosed thereto.

F. NO WAIVER OF RIGHT TO APPROPRIATELY WITHHOLD OR REDACT

29. Notwithstanding the provisions of this Confidentiality Order, any of the Parties may redact from any document, whether or not designated Confidential Information under this Order, any information containing privileged material or material protected by work-product immunity, or any information that is non-responsive to the issues in this case (such as information related to products other than the NDA and ANDA products at issue in this case).

G. AMENDMENT

30. This Confidentiality Order may be amended with respect to (a) specific documents or items of Confidential Information or (b) persons to whom Confidential Information may be disclosed, upon written agreement of the Parties with the approval of the Court. This Confidentiality Order shall remain in force and effect indefinitely until modified, superseded, or terminated by order of this Court.

H. OTHER REMEDIES

31. Nothing herein shall prevent any Party or nonparty from seeking additional or different relief from the Court not specified in this Order.

I. MISCELLANEOUS

32. No Party shall be responsible to another Party for any use made of information that was produced and not designated as Confidential Information except to the extent a Party is required to perform the duties set forth in Paragraph 5 above.

33. Nothing in this Confidentiality Order shall prejudice the right of any Party to oppose production of any information for lack of relevance, privilege, legal limitations imposed by any applicable law, or any ground other than that such information is Confidential Information as defined in this Confidentiality Order.

34. Nothing in this Confidentiality Order shall prejudice the right of any Party to seek at any time a further order modifying this Confidentiality Order.

35. In the event that a new party is added, substituted, or brought in, this Confidentiality Order will be binding on and inure to the benefit of the new party, subject to the right of the new party to seek relief from or modification of this Confidentiality Order.

36. Notice under this Confidentiality Order shall be to the Parties as follows, unless this provision is modified by the Parties in writing and filed with this Court: notice to ARI shall be made to Dennies Varughese, 1101 K St NW, 10th Floor, Washington, DC 20005, dvarughese@sternekessler.com; notice to Accord shall be made to Michael S. Weinstein, 127 Public Square, Suite 4900, Cleveland, OH 44114, mweinstein@beneschlaw.com; notice to Aspiro shall be made to W. Blake Coblentz, 2001 M Street, NW, Suite 500, Washington, DC 20036, wcoblentz@cozen.com; notice to Cipla shall be made to Steven M. Coyle, 20 Church Street, 22nd Floor, Hartford, CT 06103, scoyle@cantorcolburn.com; notice to DRL shall be made to Autumn N. Nero, 33 East Main Street, Suite 201, Madison, Wisconsin 53703-3095, anero@perkinscoie.com and SeleniousAcid@perkinscoie.com;

dshelhoff@pergamentcepeda.com; notice to Gland shall be made to Timothy H. Kratz 1050 Crown Pointe Parkway, Suite 500, Atlanta, GA 30338, tkratz@kratzandbarry.com; notice to Hikma shall be made to C. Kyle Musgrove, 40 W 24th Street, Suite 6N, New York, New York 10010, kmusgrove@geminilaw.com; notice to RK Pharma shall be made to Corey Weinstein, 2050 M St. NW Washington, DC 20036, CWeinstein@wiley.law; notice to Somerset shall be made to Kurt Mathas, 35 W. Wacker Dr., Chicago, Illinois 60601, kmathas@winston.com; notice to Sun shall be made to Samuel T. Lockner, Capella Tower, Suite 4200, 225 South Sixth Street, Minneapolis, Minnesota 55402, slockner@carlsoncaspers.com; notice to Xiromed shall be made to Jonathan A. Harris, 155 Seaport Blvd., Boston, MA 02110, jaharris@nutter.com; notice of Zydus shall be made to Zhibin Li, 640 5th Avenue, 9th Floor New York, NY 10019-6102, zhibin.li@bipc.com.

SO ORDERED.

s/ Cathy L. Waldor

Honorable Cathy L. Waldor, U.S.M.J.

Dated: January 28, 2025

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EXHIBIT A

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

_____	X
	:
IN RE SELENIOUS ACID LITIGATION	: Honorable Brian R. Martinotti, U.S.D.J.
	:
	: Civil Action No. 24 CV 7791 (BRM) (CLW)
	: consolidated
	:
	:
	:
	:
_____	X

DECLARATION OF COMPLIANCE

I, _____ do declare and state as follows:

1. I am employed as (state position)

_____ by (state name and address of employer)

_____.

2. I have read the Confidentiality Order entered in the above captioned case, a copy of which has been given to me.

3. I understand and agree to comply with and be bound by the provisions of the Confidentiality Order, including that upon receipt of any Confidential Information, I will be personally subject to the Confidentiality Order, and to all of its requirements and procedures.

4. I agree that if I receive Confidential Information pursuant to the Confidentiality Order I will not use it for any business, regulatory, commercial, or competitive purposes, including, but not limited to, filing or prosecuting patent applications or filings with the FDA concerning Citizen's Petitions as limited by the Confidentiality Order.

5. I agree that I will be subject to the jurisdiction of the United States District Court for the District of New Jersey for purposes of enforcement of the Confidentiality Order.

6. I understand that unauthorized disclosure of any designated Confidential Information, or its use for any purpose other than the above captioned case, may constitute contempt of this Court and may subject me to sanctions or other remedies that may be imposed by the Court and or potential liability in a civil action for damages by the Producing Party or Designating Party.

7. At the final termination of the above captioned case, I will return to counsel or destroy all documents or things consisting of or containing Confidential Information that I received pursuant to the Confidentiality Order, subject to Paragraph 25 of the Confidentiality Order.

I declare, as provided by 28 U.S.C. Section 1746, under penalty of perjury, under the laws of the United States of America, that the foregoing is true and correct.

Executed this ____ day of _____, 202__.

EXHIBIT B

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE SELENIOUS ACID LITIGATION

X
:
: Honorable Brian R. Martinotti, U.S.D.J.
:
: Civil Action No. 24 CV 7791 (BRM) (CLW)
: consolidated
:
:
:
:
X

DECLARATION OF COMPLIANCE

I, _____ do declare and state as follows:

1. I live at _____. I am employed as (state position)
_____ by (state name and address of employer)
_____.

2. I have read the Confidentiality Order entered in the above captioned case, a copy of which has been given to me.

3. I understand and agree to comply with and be bound by the provisions of the Confidentiality Order, including that upon receipt of any Confidential Information, I will be personally subject to the Confidentiality Order, and to all of its requirements and procedures.

4. I agree that I will be subject to the jurisdiction of the United States District Court for the District of New Jersey for purposes of enforcement of the Confidentiality Order.

5. I understand that unauthorized disclosure of any designated Confidential Information—or its use for any purpose other than the above captioned case—may constitute

contempt of this Court and may subject me to sanctions or other remedies that may be imposed by the Court and or potential liability in a civil action for damages by the Producing Party or Designating Party.

6. At the final termination of the above captioned case, I will return to counsel or destroy all documents or things consisting of or containing Confidential Information that I received pursuant to the Confidentiality Order.

I declare, as provided by 28 U.S.C. Section 1746, under penalty of perjury, under the laws of the United States of America, that the foregoing is true and correct.

Executed this ____ day of _____, 202__.
